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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-15-0963]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and

assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

Colorectal Cancer Control Program Indirect/Non-Medical Cost Study (OMB No. 0920-0963, exp. 4/30/2014) – Reinstatement – National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Colorectal Cancer (CRC) is the second leading cause of cancer-related deaths in the United States, following lung cancer. Regular CRC screening is now recommended for average-risk persons. While screening rates have increased over the past decade, screening prevalence is still lower than desirable, particularly among individuals with low socioeconomic status. In 2009, the Centers for Disease Control and Prevention (CDC) designed and initiated the population-based Colorectal Cancer Control Program (CRCCP) at 29 sites. The goals of the program are to reduce health disparities in CRC screening, incidence and mortality by promoting CRC screening for the eligible population and providing CRC screening to low-income adults over 50 years of age who have no health insurance or inadequate health insurance for CRC screening.

In 2013 CDC received Office of Management and Budget (OMB) approval to conduct a study to measure the time and costs incurred by patients screened for CRC (OMB No. 0920-0963, exp. 4/30/2014). Understanding the indirect and non-medical costs associated with CRC screening may provide insights on the barriers to screening participation. Information has been collected, however, the target number of respondents was not achieved during the initial approval period. CDC requests OMB approval to reinstate the information collection for one year in

order to meet recruitment goals and complete the data analysis as outlined in the original approval.

Information will be collected from a subset of patients enrolled in the CRCCP. Those who undergo screening by FIT or colonoscopy will be asked to complete a specialized questionnaire about the time and personal expense associated with their screening. The FIT questionnaire is estimated to take about 10 minutes. The Colonoscopy questionnaire, which includes additional questions about the preparation and recovery associated with this procedure, has an estimated burden per response of 25 minutes. Demographic information will be collected from all patients who participate in the study.

CDC plans to conduct the information collection in partnership with providers in four states (Alabama, Arizona, Georgia, and Pennsylvania). Providers will be reimbursed for patient navigator time and administrative expense associated with data collection.

The target number of responses for the overall study will result in 300 completed Colonoscopy Questionnaires and 290 completed FIT Questionnaires. To complete the study CDC plans to

collect an additional 150 Colonoscopy Questionnaires and an additional 177 FIT Questionnaires.

This information collection will be used to produce estimates of the personal costs incurred by patients who undergo CRC screening by FIT or colonoscopy, and to improve understanding of these costs as potential barriers to participation. Study findings will be disseminated through reports, presentations, and publications. Results will also be used by participating sites, CDC, and other federal agencies to improve delivery of CRC screening services and to increase screening rates among low-income adults over 50 years of age who have no health insurance or inadequate health insurance for CRC screening.

OMB approval is requested for one year. Each respondent will have the option of completing a hardcopy questionnaire or an on-line questionnaire. No identifiable information will be collected by CDC or CDC's data collection contractor. Participation is voluntary and there are no costs to respondents other than their time. The total estimated annualized burden hours are 93.

Estimated Annualized Burden Hours

Type of Respondent	Form Type	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)
Patients Served by the Colorectal Cancer Control Program	FIT questionnaire	177	1	10/60
	Colonoscopy questionnaire	150	1	25/60

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